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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,105

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Isao Yamazaki

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24956

7590

02/10/2009

MATTINGLY, STANGER, MALUR & BRUNDIDGE, P.C.

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SUITE 370

ALEXANDRIA, VA 22314

EXAMINER

TURK, NEIL N

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/614,105	Applicant(s) YAMAZAKI ET AL.	
	Examiner NEIL TURK	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on December 9th, 2008. Claims 13-18 are pending. Claims 1-12 have been cancelled.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9th, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites an automatic analyzer for analyzing a reaction of a sample and a reagent in a reaction cell, however, the body of the claim does not recite an analyzer for such. It is thereby unclear how automatic analysis is

done. Does Applicant implement a light source and detector connected to a control means for such automatic analysis?

Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how each of the plurality of reagent disks has first and second reagent dispensing probes, such that the claim only recites first and second reagent dispensing probes. Does Applicant intend to recite a plurality of reagent disks, wherein each of the plurality of reagent disks have first and second reagent dispensing probes arranged as claimed? As currently recited, the recitation to more than two reagent dispensing probes (i.e. each disk having two probes) is unclear as the claim sets forth that there are two probes, then goes on to recite that each disk has two dispensing probes. Clarification is required.

Claim 13 recites the limitation "one analysis item". There is insufficient antecedent basis for this limitation in the claim.

Claim 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what Applicant means the recitation in claim 13 of, "...wherein one analysis item is analyzed by using reagents in reagent containers arranged on the same reagent disk." This recitation is drawn to a process

limitation and there is no further structure to the automatic analyzer given. Further, it is unclear how an analysis item may be analyzed by merely using reagents in reagent containers arranged on the same reagent disk. Does Applicant intend recite an analyzer at a particular location in the automatic analyzer arranged as claimed?

Further, the claim points to a particular analysis item, but the body of the claim does not establish an analysis item (or plurality thereof) as a positive element of the automatic analyzer. How is an analysis item (or a plurality thereof) defined and related within the device?

Claims 16-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation to the reagent containers storing the first and second reagents in a package is unclearly recited. From Applicant's specification, it appears that the reagents (nor the package) is a positive element of the device. Applicant's pre-grant publication (US 2004/0105783) in paragraph [0017] recites that the reagent containers may be constructed such that it can store in a single package both of a first reagent and a second reagent. This disclosure is related to the configuration of the reagent container. Applicant should amend the claims to recite that the reagent containers are configured to or constructed in such a way so as to allow a package to be contained therein which has both the first and second reagent. As such, prior art which discloses reagent containers that are capable of holding a package with first and second reagent will be said to read on the limitations of claims 16-18.

Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16-18 recite that each of the reagent containers stores both the first and the second reagents in a package; however it is unclear how the reagents are stored in a package as first and second reagents. Is there a dividing structure in the package that allows for them to be packaged as first and second reagents? Does Applicant intend to recite that the first and second reagents are stored as a reagent solution in a package? Clarification is required.

Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how first and second reagent is taken from the packages. What structure is provided for piercing or gaining access to the reagents that are packaged? Does Applicant intend to claim a piercing structure attached to the dispensing probes for accessing the reagents therein. Further, claims 16-18 are unclear in how each of the dispensing probes relates to the first and second reagents stored in each package. Claim 13 recites that a first reagent dispensing probe is arranged to dispense the first reagent and a second reagent dispensing probe is arranged to dispense a second reagent. Now that claims 16-18 provide both first and second reagents in a single package, it is unclear how the first and second dispensing probes may function as recited. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as obvious over Ohishi et al. (6,019,945), hereafter Ohishi, in view of Ginsberg et al. (4,234,538), hereafter Ginsberg.

Ohishi discloses a sample analysis system. Ohishi shows in figure 3 a controlled (connected to computer 6b and control unit 40) analysis unit 3B in which there are a

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plurality of reagent disks 26a, 26b. Ohishi also shows a plurality of reagent dispensing probes 8a, 8b arranged to suck reagent from one of the reagent containers (12a, 12b; which are capable of holding first and second reagents in a package), and inject the reagent into one of the reaction cells 46b (within reactor section 5b). Examiner further asserts that the reagent dispensing probes are arranged to inject reagent from the reagent container into the reaction cell arranged at the same position of the reaction disk such that the reagent dispensing probes may be swiveled (also vertically movable; the moving mechanism encompassing the pipetter nozzle, shaft, and structural connections allowing for such swiveling and vertical movement) to place reagent in the same reaction cell 46 at the same position (lines 23-67, col. 6; lines 1-13, col. 7, fig. 3). With regard to claim 4, Ohishi disclose several units (3A, 3C, 3D, 3E, 3F, and 3G) with such elements for performing single analyses. With regards to claims 5 and 8, Applicant has not positively recited a rail extending over the reagent disks, and the railing is not established as an element of the device, the claims only recite an intended use for the moving mechanism, and intended uses are not afforded patentable weight.

Ohishi does not disclose including first and second reagent dispensing probes arranged at each of the reagent disks.

Ginsberg discloses an automatic analyzer that includes first and second reagent dispensers 44, 46 arranged about a reagent disc 42 (abstract; lines 20-32, col. 5, fig. 1).

It would have been obvious to modify Ohishi to include first and second reagent dispensing probes arranged at a disk, such as taught by Ginsberg in order to provide a second available, and clean dispensing probe that is available for immediate use on the

next progression. Further, it would be obvious to apply this to both reagent disks of Ohishi (26A and 26B) so that a second, clean dispensing probe would be available to both of the first and second reagents contained at the reagent disks 26A, 26B; thereby throughput would increase as fewer cleaning steps for the dispensing probes would be required and more probes would be available to dispense reagent into the reaction containers within the reaction disk.

Examiner asserts that the recitation to only one of said first and second dispensing probes sucking first or second reagent during a predetermined cycle is drawn to a functional limitation not afforded patentable weight in the device claims. Examiner asserts that the combination of Ohishi in view of Ginsberg discloses the recited structural elements of the claim and is thereby said to be capable of such a function. Further, Applicant has not established the specific control function by the controller for such a recitation. The recitation of, "...a controller for controlling operations of said first and second dispensing probes" does not provide the that controller is specifically configured to control the dispensing probes such that only one of said first and second dispensing probes suck first or second reagent during a predetermined cycle. The generic recitation to "for controlling operations" does not show that such operations include that described above.

Claims 15 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohishi in view of Ohishi in view of Ginsberg as applied to claims 13,14, 16, and 17 and in further view of Minekane (4,808,380).

Ohishi/Ginsberg does not disclose at least one reagent disk arranged inside a reaction disk.

Minekane discloses an automatic chemical analyzing apparatus. Minekane discloses a cuvette rotor 18 in which cuvettes 20 are mounted in an annular array to receive sample and reagent to be then analyzed by a photometer (reaction disk 18 with reaction cells 20). Minekane further discloses reagent supply 14, which has a pair of coaxial reagent rings 24 and 26, and is placed peripherally within the ring of cuvette arrays (arranged inside the reaction disk) (lines 19-67, col. 2, fig. 1).

It would have been obvious to modify Ohishi /Ginsberg to arrange reagent disks inside the reaction disk such as taught by Minekane in order to save space and optimize the workspace area.

Response to Arguments

Applicant's arguments with respect to claim 1-12 have been considered but are moot in view of the new ground(s) of rejection. As claims 1-12 have been cancelled, such arguments are moot, and new claims 13-18 have been rejected as discussed above. New claims 13, 14, and 16-18 are rejected under 35 USC 103(a) over Ohishi in view of Ginsberg, and claim 15 is rejected under 35 USC 103(a) over Ohishi in view of Ginsberg and in further view of Minekane.

Applicant argues that the Ohishi in view of Ginsberg does not disclose "only one of the first and second reagent dispensing probes for each of said reagent disks sucks

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said first or second reagent...during a predetermined cycle." Examiner asserts that such a recitation is drawn to a functional limitation not afforded patentable weight in a device claim. Such that Ohishi in view of Ginsberg discloses the recite structural elements, Ohishi/Ginsberg is said to be capable of such a function. Examiner further notes, as discussed above, that Applicant has not provided a controller configured for such control as the generic recitation to a controller configured "for controlling operations of said first and second dispensing probes" does not recite that such operations include that described above.

With regards to claim 15, Examiner argues that the combination of Ohishi in view of Ginsberg and in further view of Minekane reads on the claim limitations. Minekane discloses a reaction disk 18 with reaction cells 20 and reagent disk, such as disk 24 arranged inside of the reaction disk. Thereby, the combination as discussed above, meets the recitation to a reagent disk being arranged inside a reaction disk. Examiner asserts that Minekane thereby shows that arrangement of a reagent disk inside a reaction disk provides to save space, thus optimizing the workspace.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1795